

§ 721.2097

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80 (f), (v)(1), (w)(1), and (y)(1).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

[61 FR 63736, Dec. 2, 1996]

§ 721.2097 Azo chromium complex dye-stuff preparation (generic name).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as an azo chromium complex dye-stuff preparation (PMN P-95-240) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial and consumer activities.* Requirements as specified in § 721.80 (v)(1), (v)(2), (w)(1), (w)(2), (x)(1), and (x)(2).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

[61 FR 63736, Dec. 2, 1996]

§ 721.2098 Aliphatic polycarboxylic acid metal salt (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as an aliphatic polycarboxylic acid metal salt (PMN P-01-7) is subject to reporting under this section for the

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significant new use described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(v)(1), (x)(1), and (f).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a), (b), (c), and (i) are applicable to manufacturers, importers, and processors of this chemical substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

[68 FR 70176, Dec. 17, 2003]

§ 721.2120 Cyclic amide.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as a cyclic amide (PMN P-92-131) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Release to water.* Requirements as specified in § 721.90 (a)(4), (b)(4), and (c)(4) (concentration set at 70 ppb).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping requirements.* Requirements as specified in § 721.125 (a), (b), (c), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

[57 FR 46465, Oct. 8, 1992, as amended at 58 FR 34204, June 23, 1993]

§ 721.2121 Thiosubstituted carbonate ester (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as Thiosubstituted carbonate

ester (PMN P-99-0654) is subject to reporting under this section for the significant new use described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Release to water*. Requirements as specified in § 721.90 (a)(1), (b)(1), and (c)(1).

(ii) [Reserved]

(b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125 (a), (b), (c), and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements*. The provisions of § 721.185 apply to this section.

[65 FR 81399, Dec. 26, 2000]

§ 721.2122 Substituted phenyl azo substituted sulfo carbopolycycle.

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance identified generically as a substituted phenyl azo substituted sulfo carbopolycycle (PMN P-96-702) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80(r) (204,000 kg) (activated sludge adsorption isotherm- OPPTS 835.1110 test guideline (public draft; 61 FR 16486, April 15, 1996) (FRL-5363-1), daphnid acute toxicity-§ 797.1300, fish acute toxicity-§ 797.1400, murine immune allergic response study (*Toxicology and Applied Pharmacology* 112:190-197 (1992))). A person may not manufacture or import the substance beyond the following aggregate production volume limits, unless that person conducts the following corresponding studies on the substance and submits all final reports and underlying data in accordance with the procedures and criteria specified in paragraphs (a)(2)(i)(A), (a)(2)(i)(B), (a)(2)(i)(C), and (a)(2)(i)(D) of this section.

(A) Each study required to be performed pursuant to this section must be scientifically valid. *Scientifically*

valid means that the study was conducted according to:

(1) The test guidelines specified in paragraph (a)(2)(i) of this section.

(2) An EPA-approved protocol.

(3) TSCA Good Laboratory Practice Standards at 40 CFR part 792.

(4) Using methodologies generally accepted at the time the study is initiated.

(5) Any deviation from these requirements must be approved in writing by EPA.

(B) Before starting to conduct any of the studies in paragraph (a)(2)(i) of this section, the person must obtain approval of test protocols from EPA by submitting written protocols. EPA will respond to the person within 4 weeks of receiving the written protocols. Published test guidelines specified in paragraph (a)(2)(i) of this section (e.g., 40 CFR part 797 or part 798) provide general guidance for development of test protocols, but are not themselves acceptable protocols.

(C) The person shall:

(1) Conduct each study in good faith with due care.

(2) Promptly furnish to EPA the results of any interim phase of each study.

(3) Submit, in triplicate (with an additional sanitized copy, if confidential business information is involved), the final report of each study and all underlying data ("the report and data") to EPA no later than 14 weeks prior to exceeding the applicable production volume limit. The final report shall contain the contents specified in 40 CFR 792.185.

(D)(1) Except as described in paragraph (a)(2)(i)(D)(2) of this section, if, within 6 weeks of EPA's receipt of a test report and data, the person receives written notice that EPA finds that the data generated by a study are scientifically invalid, the person is prohibited from further manufacture and import of the PMN substance beyond the applicable production volume limit.

(2) The person may continue to manufacture and import the PMN substance beyond the applicable production limit only if so notified, in writing, by EPA in response to the person's compliance with either of the following